

DETAILED ACTION

Status of Claims

1. Claims 1, 2, 4 – 8 and 10 - 20 are pending.

Claims 3, 9, 21 and 22 have been canceled

Claims 1, 2, 4 – 8 and 10 - 20 are rejected.

Response to Amendment

2. The amendment to claim 8, submitted November 2, 2009 is acknowledged and entered.

Response to Arguments

3. Applicant's arguments filed November 2, 2009, with regards to the 35 USC 103(a) rejections of claims 1, 2, and 4 - 7 have been fully considered but they are not persuasive, for the reasons set out in the Office Action mailed July 2, 2009 and as set out below.

4. Applicant's arguments filed November 2, 2009, with regards to the 35 USC 103(a) rejections of claims 8, and 10 - 20 have been fully considered but they are not persuasive, for the reasons set out in the Office Actions mailed October 15, 2008 and July 2, 2009 and as set out below.

Claim Rejections - 35 USC § 103

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

Art Unit: 1621

3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
7. Claims 1, 2 and 4 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghisalberti (WO 2001/18161) in view of Saebo et al. (US 6,410,761), for the reasons set out in the Office Action mailed July 2, 2009, and set out below.
8. Applicant respectfully asserts that the optional refining process of Ghisalberti relates to the deodorization of the final product and in no manner teaches or suggests enriching the product stream with the desired CLA isomers, via fraction column and a heater.
9. In response, the Examiner interprets Applicant's claims in the broadest possible manner. As such, claim 1 does not limit the product stream to CLAs of c9, t11 and t10, c12 isomers. Ghisalberti's teaches a method for producing CLA from vegetable oil, wherein the product mixture produced is enriched in CLA isomers of c9,c11, c9,t11 and c10,c12 and t10,c12. (see page 8, lines 5-11). Further, Ghisalberti states that in order

Art Unit: 1621

to obtain a high grade CLA, a more purified form of the enriched CLA product, vacuum distillation techniques can be used. The use of vacuum distillation techniques, at the time of Ghisalberti would have included the use of known apparatus such as a fractionation column. Additionally, the use of distillation at low residence time is taught by Saebo et al. for the purpose of obtaining purer CLA product. It is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. (In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792,794, 215 USQP 569,570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983)). In this instance, the prior art teaches that distillation, at low residence time can be used to obtain a purer CLA with Applicant's claimed isomer forms.

10. Applicant respectfully asserts that Reaney et al. undermines the Examiner's position by teaching that the products of distillation at temperatures above 226°C were found to contain a series of undesirable CLA products, and concluded that distillation was not appropriate

11. In response, even though Reaney et al. states that the undesirable CLA isomers formed when distillation occurred at that temperature, a peak comparison Fig. 3, Fig. 2C and Fig. 2 indicates that c9, t11 and t10, c12 isomers remain at some level. Further, from Reaney et al. there is no indication of how long the CLA in there process was held at the elevated temperatures. This is an important factor because according to

Art Unit: 1621

Applicant's Exhibit A (Sebedio et al. , AOCS 2003), residence time in conjunction with temperature has an affect on the outcome of the refining process for CLA isomers. Also, because Saebo et al, teaches that elevated temperatures between 180 to 200°C for several hours should be avoided. Thus, if the process of Reaney et al. held the CLA isomers in the distillation column for a prolonged period of time, based on the teachings of Sebedio et al. and Saebo et al., the Reaney et al. process would naturally cause the formation of undesirable isomers.

12. Furthermore, the Examiner notes that in the Specification, Applicant describes there distillation apparatus as a low residence time distillation apparatus. Limitations appearing in the specification but not recited in the claim should not be read into the claim. (E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003)). However, where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. (Toro Co. v. White Consolidated Industries Inc., 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999)). Sebedio et al. and Saebo et al. both suggest low residence time when working with CLA at elevated temperatures of 200°C or above because undesirable trans, trans isomers form. No invention is involved in following the teaching of the prior art, even if the results obtained are better than might have been expected. (In re Lieser, 74 USPQ 104, 162 F2d 224 (CCPA 1947); In re Gauerke, 31 USPQ 330, 87 F2d 330 (CCPA 1936); In re Kepler, 56 USPQ 177, 132 F2d 130 (CCPA 1942); In re Carothers et al., 57 USPQ 277, 135 F2d 343 (CCPA 1946); & In re Leum et al., 72 USPQ 127, 158 F2d 311 (CCPA 1943)). Therefore, Applicant's claimed

invention is deemed to be obvious absent a showing of unexpected results. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

13. Claims 8 and 10 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saebo et al. (US 6,410,761) in view of Baltes et al. (US 3,162,658), in view of Sachtler (US 5,326,925) and further in view of Ghisalberti (WO 2001/18161), for the reasons set out in the Office Action mailed October 15, 2008, July 2, 2009; and as set out below.

14. The rejected claims cover, inter alia, a process to produce a refined conjugated linoleic acid-containing material, comprising: transesterification of a linoleic acid-containing oil to generate a composition containing linoleic acid esters; isomerization of the composition containing linoleic acid esters to form a first stream containing c9,t11 and t10,c12 isomers of conjugated linoleic acid esters; and distillation of the first stream in a distillation apparatus comprising a fractionating column and a heater operated at a temperature in the range of 240°C to 270°C, to produce a second stream enriched in the c9,t11 and t10,c12 isomers of conjugated linoleic acid esters compared to the first stream. Rejected claims 10 - 15 disclose the isomerization catalyst, and isomerization reaction temperature. Rejected claims 17-20 are drawn to the work up and optimization of the process. Rejected claim 16 discloses the various linoleic acid containing oils used in the process.

15. Saebo et al. discloses process for producing a novel composition of conjugated linoleic acid (CLA) ester with the isomers c9,t11-octadecanoic acid ester and t10,c12 – octadecanoic acid ester, that were obtained by the direct isomerization of an unrefined linoleic acid. (see column 6, lines 16 - 23). In the process of Saebo et al. after the conjugation reaction the resulting CLA containing composition may be further purified. In the purification process, the resulting CLA is distilled at 190°C in a molecular distillation plant at a vacuum of 10^{-1} to 10^{-2} milibar (0.075 to 0.008 mmHg). Saebo et al. states that the advantage of the purification system is that it takes a shorter time, less than a minute. (see column 10, lines 9 – 37). The preferred oil for conjugation are sunflower and safflower oil, other seed oils such as corn, soybean and linseed oils may also be used in Saebo's process. (see column 4,lines 53-54 & lines 57-58).

Saebo's process discloses that the process provides for the formation of the CLA ester by an esterification process involving methanol or ethanol or other branched or straight chain monohydric alcohols. (see column 12, lines 44 - 45 & lines 56 - 57). In the nonaqueous alkali isomerization of the CLA ester of Saebo et al., alkali alcoholate catalyst are used, such as, sodium or potassium ethoxide or their methyl, butyl, or propyl counterparts. (see column 12, lines 50- 55). The isomerization temperature ranges from 130 to 165°C. (see column 9, lines 48 – 49). Example 9 teaches the process for large scale batch production of conjugated safflower fatty acid methyl ester, wherein the process is a two step process involving the first step of methanolysis (transesterification), and the second step of conjugation (isomerization). Table 15 and 16 disclose the resulting CLA esters having a greater amount of c9,t11 and t10,c12

Art Unit: 1621

isomers. (see peak #s 9 and 10). Even though Example 9 does not show that the conjugated safflower fatty acid methyl ester was further purified after the conjugation reaction, the invention of Saebo et al. discloses that purification by distillation of the derived novel conjugated linoleic acid-containing compositions may be conducted. (see column 3, lines 66-67 to column 4, lines 1-13). In Example 9 transesterification is completed sequentially, with transesterification taking place first, side products are removed, then the alcohol and alkali alcoholate catalyst are added to the reactor to conjugate the ester. Further, Saebo et al. teaches that distillation at elevated temperatures between 180 and 200°C for long periods of time should be avoided. (see column 10, lines 31 – 35).

16. Saebo et al. fails to specifically disclose the following: the use of calcium alkoxide salt; the catalyst is a solid or solution in a conjugated alcohol of the alkoxide; the transesterification and isomerization steps are performed in one reaction vessel concurrently; the transesterification and isomerization steps occur concurrently using dual reaction zones; and use of a fractionating column with a heater operated at temperatures of 240°C to 270°C in the distillation step.

17. However, Baltes et al. discloses an isomerization process for the production of conjugated poly-ethenoid acids and uses the following alkali metals for the alcoholate catalyst: cesium, rubidium, potassium, sodium, lithium, magnesium and zinc. (see column 2, lines 39-45). It is stated that organic alkali metal compounds can be used as catalyst. Also, in Example 1 of Baltes, dried potassium methylate (solid) is used and isomerization and transesterification take place at the same time in one reaction vessel.

Art Unit: 1621

Like Saebo et al., Baltes et al fails to list calcium, however, based on the periodic family both references include members of that periodic group, one skilled in the art would have been motivated to vary the reaction process, such as by using the calcium as a cation for the alkoxide as a matter of choice based on such factors as the success of other family members in the isomerization reaction. (column 9, lines 55-63).

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention to produce a refined conjugated linoleic acid-containing material as suggested by the process of Saebo et al. and modify the isomerization as suggested by the process of Baltes, to achieve the claimed invention. As disclosed in Saebo et al. motivation for the combination would be to provide a starting point for design of the individual process for the production of the desired compositions containing conjugated linoleic acid.

Therefore, the invention as a whole was *prima facie* obvious because a person of ordinary skill in the art at the time the invention was made, would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

18. With regards to the processing step that uses a dual reaction zone apparatus for transesterification and isomerization occur concurrently, Sachtler discloses a process in Example 3 that uses a dual zone reaction system in its isomerization process. Even though the process of Sachtler does not involve the isomerization of an identical composition, however, it has been held that a prior art reference be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem

Art Unit: 1621

with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *in re Oetiker*, 997 F.2d 1443, 24 USPQ 1443 (Fed. Cir. 1992). In this case, applicant is concerned with isomerization of one form of linoleic acid ester to form another form of the linoleic acid ester, while Sachtler was concerned with the isomer 2,3-dimethylbutane. In Sachtler the effluent of a single reaction zone provided the feed for the second reaction zone. As such, it would have been obvious to one of ordinary skill at the time of the claimed invention, knowing that the transesterification and isomerization process can occur sequentially, that a dual reaction apparatus would be successful based on its successful use in the isomerization process of Sachtler. Basically, the transesterification product (linoleic acid ester) provided feed to the second reaction zone where isomerization would take place.

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991). Therefore, this limitation is considered obvious.

19. With regards to the use of a fractionating column with a heater operated at temperatures of 240°C to 270°C in the distillation step, the Examiner turns to the teaching of Ghasalberti. Ghisalberti discloses a process for the preparation of conjugated linoleic acid (CLA) where the term CLA includes the ester form of

Art Unit: 1621

conjugated linoleic acid. (see page 4, lines 13-16). In the process of Ghisalberti, in order to obtain high grade CLA the product is refined by conventional refining techniques which include stripping as vacuum distillation techniques or the like. (see page 7 lines 24-25 to page 8 lines 1-3). The process produces a product enriched in CLA isomers where c9,c11, c9,t11 and c10,c12 and t10,c12 are most abundant in the mixed CLA. (see page 8, lines 5-11).

20. Ghisalberti does not specifically disclose the use of a fractionating column with a heater operated at temperatures of 240°C to 270°C; however, Ghisalberti's process can use standard distillation means, which would include the use of known apparatus such as a fractionation column. Ghisalberti states that these conventional means are used to refine CLA and its derivatives. Also, it obtains an enriched product. Applicant's claim 8 obtains a product enriched in c9,t11 and t10,c12. However, from the teachings of Ghisalberti, it is known that isomers of CLA remain after distillation. As such, one skilled in the art would expect that since Applicant is merely using conventional distillation that even though they are enriching the amount of c9,t11 and t10,c12, just like the teachings in Ghisalberti, other isomers will remain. Additionally, in the view of the fact that the claims do not limit the isomers in the ester product to the c9,t11 and t10,c12 isomers.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the process of Saebo et al. and use a known technique, fractionation one of the conventional distillation techniques as suggested by Ghisalberti to refine CLA, since Ghisalberti states that like distillation techniques can be used, and achieve enriched CLA esters with a reasonable expectation of success.

21. Thus, the claims would have been obvious because the technique for preparing CLA using transesterification, isomerization the refining CLA using distillation is generally suggested by the teaching of Saebo et al. Further, purification of the CLA to provide an enriched CLA using other distillation technique such as fractional distillation, was suggested by Ghisalberti and part of the ordinary skill in the art, at the time of Applicant's claimed invention. In applying known technique to a known device (method, or product) ready for improvement to yield predictable results, the claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. The Supreme Court in *KSR* noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then the resulting invention would not have been obvious because one of ordinary skill could not have been expected to achieve it.

22. With regard to the distillation operating temperatures of 240°C to 270°C, it would be within the purview of one skilled in the art to adjust the operating temperature in the distillation process to obtain the desired purity in view of the fact that Ghisalberti states that distillation can be used to refine the CLA. Additionally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)).

Therefore, all the claimed elements were known in the prior arts of Saebo et al., Baltes et al., Sachtlar and Ghisalberti; and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, that is to modify the process of Saebo et al. using another distillation technique at a low residence time when heated, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

KSR International Co. v. Teleflex Inc., 550 U.S. ___, 82 USPQ2d 1385 (U.S. 2007).

Response to Applicant's Comments

23. Applicant respectfully asserts that the Sebedio et al. article submitted as Exhibit A in teaching that new isomers can be achieved by varying the temperature does not provide guidance for how to increase the content of the desired c9,t11 and t10,c12 isomers. Further, that Exhibit A supports the fact that desirable isomers undergo rearrangement to undesirable isomers and temperatures of 220°C, thus conducting distillation at elevated temperatures would not have been considered by one of ordinary skill in the art. Especially in light of the teaching of Reaney.
24. In response, the Examiners states that Sebedio et al. points out that it was a known fact that various temperatures affected the isomer arrangement of CLA and according to Sebedio et al. chemist use this to produce the desired isomers. Also, the reference states that this rearrangement is more likely to occur with prolonged heating at the elevated temperature. This teaching corresponds to the teaching of Saebo et al. that distillation process at elevated temperatures for prolonged periods of time cause rearrangement to undesirable trans, trans isomers. Thus, not only is temperature a

factor in whether rearrangement does or does not occur but, the amount of time under those specific heat conditions is a factor that affects the rearrangement of the isomer from desirable to undesirable. For this reason along with the fact that in Reaney there is no indication of how long the CLA in their process was held at the elevated temperatures, the Examiner does not find Reaney to clearly teach that fractional distillation is not appropriate. Thus, the Examiner looks to the teaching of Saebo et al. which suggest that distillation, when used as a purification step, conducted at elevated temperature with low residence time would avoid rearrangement to undesirable isomers of CLA yielding an enriched CLA product. It is well settled that a patent cannot be properly granted for the discovery of a result which would flow naturally from the teaching of the prior art. (*In re Libby*, 118, USPQ 94, 96; 255 F2d 412 (CCPA 1947)).

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1621

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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